

# Isotretinoin (Accutane®)

---

This sheet is about exposure to isotretinoin in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

## ***What is isotretinoin?***

Isotretinoin is a prescription medication taken by mouth to treat severe cystic acne that has not responded to other treatments. Isotretinoin is a form of Vitamin A. It has been sold under brand names such as Accutane®, Absorica®, Amnesteem®, Claravis®, Epuris®, Clarus®, Myorisan®, Sotret®, and Zenatane®.

## ***I take isotretinoin. Can it make it harder for me to get pregnant?***

People who are trying to get pregnant should not be taking isotretinoin. There have been reports of changes in menstrual periods in some people taking isotretinoin. There are no reports of problems getting pregnant while taking isotretinoin.

## ***I am taking isotretinoin, but I would like to stop taking it before pregnancy. How long does it stay in my body?***

People eliminate medication at different rates. In healthy adults, it takes up to 10 days, on average, for most of the isotretinoin and its by-products to be gone from the body. However, it is recommended that a person wait one month after stopping isotretinoin before trying to get pregnant.

## ***I just found out I am pregnant. Should I stop taking isotretinoin?***

YES. Stop taking the medication right away. As soon as possible, call the healthcare provider who prescribed the isotretinoin and the healthcare provider who will be taking care of you during your pregnancy. Isotretinoin can cause birth defects. Your healthcare team can talk with you about screening tests and ultrasounds that can detect some birth defects. Screening tests and ultrasound cannot tell if a child may have problems with learning or development.

## ***Does taking isotretinoin increase the chance for miscarriage?***

Miscarriage can occur in any pregnancy. The chance of having a miscarriage can be as high as 40% when isotretinoin is used in early pregnancy.

## ***Does taking isotretinoin increase the chance of birth defects?***

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Isotretinoin causes birth defects in up to 35% or more of infants whose are exposed during pregnancy. The chance of having a baby with a birth defect applies even if the medication has been taken for a short time. Most of the infants with birth defects will have small or absent ears and hearing and eyesight problems. Life-threatening heart defects and fluid around the brain are other birth defects that have been seen in some infants. Some will have a small jaw, small head, cleft palate and some will be born with a small or missing thymus gland (a gland that makes hormones).

## ***Does taking isotretinoin in pregnancy increase the chance of other pregnancy-related problems?***

An increased chance for preterm delivery (birth before week 37) has been associated with the use of isotretinoin in pregnancy.

## ***Does taking isotretinoin in pregnancy affect future behavior or learning for the child?***

Many of the children exposed to isotretinoin during pregnancy will have moderate to severe behavioral problems and/or intellectual disability. These issues usually do not get noticed at birth, but are discovered in childhood. Other possible long-term effects on exposed children are unknown.

### ***Can I still get a prescription for isotretinoin?***

Isotretinoin can be prescribed under a special program called iPLEDGE™. People MUST adhere to all requirements of the iPLEDGE program. Following are some of the requirements:

- Must be able to understand that severe birth defects can occur with use of isotretinoin.
- Must receive and be able to understand safety information about isotretinoin and the iPLEDGE requirements.
- Must sign an Informed Consent Form that contains warnings about the risks of using isotretinoin.
- Must not be pregnant or be breastfeeding.
- Must have two (2) negative pregnancy tests before starting isotretinoin.
- Must have a pregnancy test every month during treatment, and a negative test a month after treatment.
- Must use two (2) different forms of birth control at all times (unless agrees not to have sex) starting one (1) month before treatment continuing during treatment, and for one (1) month after treatment.
- Must fill their prescription within 7 days after the health care provider visit.
- Must agree to see their health care provider every month during treatment for a health check and to get a new prescription.

For more information about the iPLEDGE program call 1-866-495-0654 or visit the iPLEDGE website at <https://www.ipledgeprogram.com>.

MotherToBaby recommends that people who are not sexually active or planning a pregnancy still talk to their healthcare provider about using effective birth control methods because almost 50% of all pregnancies are unplanned or unintended.

### ***Breastfeeding while taking isotretinoin:***

There have been no studies looking at the use of isotretinoin during breastfeeding. It is not known what effect, if any, exposure to isotretinoin through the breast milk can have on a nursing infant. Breastfeeding while taking isotretinoin is not recommended. Be sure to talk to your healthcare provider about all your breastfeeding questions.

### ***If a male takes isotretinoin, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?***

Isotretinoin does not appear to affect sperm, and there have been no reports of isotretinoin causing male infertility. There have been a few reports of erectile dysfunction and ejaculatory failure in males taking isotretinoin. Studies have not been done in males to see if isotretinoin could increase the chance of birth defects. In general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

### **Selected References:**

- Adams J and Lammer EJ. 1991. Relationship between dysmorphology and neuropsychological function in children exposed to isotretinoin “in utero”. In: T. Fujii and G. J. Boer (eds), Functional Neuroteratology of Short Term Exposure to Drugs. Tokyo: Teikyo University Press, pp.159-170.
- Adams J and Lammer EJ. 1993. Neurobehavioral teratology of isotretinoin. *Reprod Toxicol.* 7(2):175-177.
- Adams J. 1996. Similarities in genetic mental retardation and neuroteratogenic syndromes. *Pharmacol Biochem Behav.* 55(4):683-690.
- Autret-Leca E et al. 2010 Isotretinoin exposure during pregnancy: assessment of spontaneous reports in France. *Drug safety : an international journal of medical toxicology and drug experience.* 33(8):659-665.
- Chelliah P and Glass D. 2020. Comprehensive review of reports of menstrual irregularities associated with isotretinoin. *Int J Women’s Derm* 6: 365-367.

- Choi EJ, Kim N et al. 2021. The rates of major malformations after gestational exposure to isotretinoin; a systemic review and meta- analysis. *Obstet Gynecol Sci* Mar 17. doi.org/10.5468/orgs.20373.
- Coleman, R and MacDonald D. 1994. Effects of isotretinoin on male reproductive system. *Lancet* 344:198.
- Committee on Drugs, American Academy of Pediatrics. 1992. Retinoid therapy for severe dermatological disorders. *Pediatrics* 90:119-120.
- Dai WS, et al. 1989. Safety of pregnancy after discontinuation of isotretinoin. *Arch Dermatol* 125:362-365.
- Dai WS, et al. 1992. Epidemiology of isotretinoin exposure during pregnancy. *J Am Acad Dermatol* 26:599-606.
- DiGiovanna JJ, et al. 1984. Etretinate: persistent serum levels of a potent teratogen. *Clin Res* 32:579A.
- Goldsmith LA, et al. 2004. American Academy of Dermatology Consensus Conference on the safe and optimal use of isotretinoin: summary and recommendations. 1: *J Am Acad Dermatol* 50(6):900-906. [Erratum in: *J Am Acad Dermatol*. 2004 51(3):348. dosage error in text.]
- Lammer EJ, et al. 1987. Risk for major malformation among human fetuses exposed to isotretinoin (13-cis-retinoic acid). *Teratology* 35:68A.
- Lammer EJ, et al. 1985. Retinoic acid embryopathy. *New Engl J Med* 313:837-841.
- Lee SM et al. 2009. A case of suspected isotretinoin-induced malformation in a baby of a mother who became pregnant one month after discontinuation of the drug. *Yonsei medical journal*.50(3):445-447.
- Loureiro KD et al. 2005 Minor malformations characteristic of the retinoic acid embryopathy and other birth outcomes in children of women exposed to topical tretinoin during early pregnancy. *American journal of medical genetics. Part A*. 136(2):117-121.
- Mitchell AA. 1992. Oral retinoids: What should the prescriber know about their teratogenic hazards among women of child-bearing potential? *Drug Saf* 7(2):79-85.
- Nulman I. 1998. Steady-state pharmacokinetics of isotretinoin and its 4-oxo metabolite: implications for fetal safety. *J Clin Pharmacol* 38:926-930.
- Recommendations for isotretinoin use in women of childbearing potential. 1991. *Teratology* 44:1-6.